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DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

CHAPTER 12

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Subchapter 2

Approval of Laboratories

37.12.201 REGISTRATION (1) Every person, firm or corporation operating or maintaining a laboratory in which body fluids, secretions or excretions are examined for the determination of the presence or absence of an infectious agent in the material examined or in the person or animal from which it was secured shall register annually with the department, giving the name of such laboratory, its location and the name of the person or persons owning or operating the same.

(2) All laboratories doing public health work in the state of Montana shall register with the department. Such laboratories which meet the standards of the department shall be listed as suitable for the tests required under Title 40, chapter 1, part 2, MCA, relating to marriage licenses, and shall be designated as approved laboratories. (History: Sec. 40-1-206 and 50-1-202, MCA; IMP, Sec. 40-1-206 and 50-1-202, MCA; Eff. 12/31/72; TRANS, from DHES, 2001 MAR p. 2246.)

Rules 02 through 04 reserved

37.12.205 APPROVAL (1) Laboratories which, after inspection, are found to conform to the standards required by the department will be given a certificate of approval, and such laboratories will thereafter be designated as approved laboratories. (History: Sec. 40-1-206 and 50-1-202, MCA; IMP, Sec. 40-1-206 and 50-1-202, MCA; Eff. 12/31/72; TRANS, from DHES, 2001 MAR p. 2246.)

37.12.206 INSPECTIONS (1) An authorized representative of the state laboratory shall make an annual inspection of all registered laboratories, and at such other times as he or the department may deem advisable. (History: Sec. 40-1-206 and 50-1-202, MCA; IMP, Sec. 40-1-206 and 50-1-202, MCA; Eff. 12/31/72; TRANS, from DHES, 2001 MAR p. 2246.)

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Subchapter 3

Licensure of Laboratories Conducting
Analyses of Public Water Supplies

37.12.301 DEFINITIONS For the purpose of this subchapter:

(1) "Accuracy" means the degree of agreement between an observed value and an accepted reference value.

(2) "Analyte" means the substance or thing for which a water sample is analyzed to determine its presence or quantity.

(3) "Bachelor degree or equivalent" means a college degree with the equivalent of 30 semester hours in a biological or physical science program or at least four years of experience in a specific related scientific discipline.

(4) "Certification officer" means a representative of the department who conducts assessments of laboratories to determine if they should be approved for licensure. The representative may be a third party contractor who acts under the authority of the department.

(5) "Chemical hygiene plan" means a document written by a laboratory that describes the procedures used to store, handle and dispose of chemicals in the laboratory.

(6) "Contaminated" means exceeding a maximum contaminant level established in ARM Title 17, chapter 38, subchapter 2.

(7) "Department" means the department of public health and human services.

(8) "Environmental laboratory" means the environmental laboratory of the department of public health and human services that is responsible for the licensing of laboratories performing drinking water analyses in Montana.

(9) "Environmental Protection Agency, (EPA)" means the United States environmental protection agency.

(10) "EPA laboratory certification manual" means the EPA publication entitled "Manual for the Certification of Laboratories Analyzing Drinking Water," March, 1997, 4th edition (EPA 815-B-97-001).

(11) "Holding time" means the maximum time that a sample may be held prior to preparation or analysis.

(12) "Interdependent analyte group" means a group of analytes, as determined by the department, for which the ability to correctly identify and quantify a single analyte in the group indicates the ability to correctly identify and quantify other analytes in the group.

(13) "Initial demonstration of analytical capability" means the procedure described in the method cited in 40 CFR part 136, appendix A, July 1998 edition, for chemistry analysis, used to determine a laboratory's accuracy and precision in applying an analytical method.

(14) "Key personnel" means a laboratory's director, supervisor and quality assurance officer, all of whom meet the requirements of the EPA laboratory certification manual.

(15) "Method detection limit" means the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero as determined from analysis of a sample containing the analyte in a given matrix as described in 40 CFR part 136, appendix B, July 1995 edition.

(16) "Performance evaluation (PE) sample" means a sample obtained through a source approved by the environmental laboratory whose composition is unknown to the laboratory performing the analysis and which is used to evaluate the ability of the laboratory to produce precise and accurate results.

(17) "Precision" means the degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves. Precision is usually expressed as standard deviation, variance or range, in either absolute or relative terms.

(18) "Quality assurance plan" means a document written by a laboratory that describes the procedures used to ensure that routinely generated analytical data are scientifically valid and that their precision and accuracy are within defined limits.

(19) "Safe Drinking Water Act" means the federal law set out in 42 USC 300f through 300j-11, governing drinking water programs.

(20) "Standard operating procedures (SOPs)" means a laboratory's written document which details the steps of an operation, analysis or action whose techniques and procedures are thoroughly prescribed and is accepted by the laboratory as the procedure for performing certain routine or repetitive tasks.

(21) "Variance" means written approval from the environmental laboratory allowing a laboratory to use a method, procedure or equipment other than that required by these rules that meets the purpose and intent of these rules and that has been shown to have no adverse material effects on the accuracy of analyses.

(22) "Waiver" means written approval from the environmental laboratory exempting a laboratory from a requirement of these rules if the environmental laboratory finds that the requirement is inapplicable to the particular practice of that laboratory. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

Rules 02 and 03 reserved

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37.12.304 LABORATORY LICENSURE: COVERAGE (1) A laboratory that conducts analyses of water from public water supplies must meet the licensure requirements of these rules before the analyses or reports of the analyses may be accepted by the department of environmental quality for the purpose of meeting the requirements of Title 75, chapter 6, MCA, and rules of the department of environmental quality concerning public water supplies.

(2) A laboratory may be licensed to perform microbiology testing, chemistry testing, or both. Microbiology testing and chemical testing are separate licensure categories. If a laboratory requests licensure for both categories, it must submit to the department a separate license application and undergo a separate inspection for each category, and it will receive a separate license for each category for which it qualifies.

(3) A license granted by the department constitutes permission to perform only those analyses of analytes which the laboratory requests the licensure to cover and that the department finds the laboratory is capable of performing in accordance with the provisions of this subchapter. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

37.12.305 PROCEDURE FOR LICENSURE (1) Any laboratory not currently licensed but desiring licensure under this subchapter must:

(a) submit a completed application to the Department of Public Health and Human Services, Public Health and Safety Division, Environmental Laboratory, 1400 Broadway, Cogswell Building, P.O. 202951, Helena, MT 59620-2951, on forms provided by the department. The application must include:

(i) the legal name of the laboratory;

(ii) the name of the laboratory owner;

(iii) the laboratory mailing address;

(iv) the full address of the physical location of the laboratory;

(v) the laboratory hours of operation;

(vi) a description of qualifications of key personnel and technical employees;

(vii) the name and daytime phone number of the laboratory director;

(viii) the name and daytime phone number of the laboratory's quality assurance officer;

(ix) the name and daytime phone number of the laboratory contact person; and

(x) the laboratory's quality assurance plan and documentation of the laboratory's implementation and adherence to the quality assurance plan.

(b) be enrolled in a proficiency testing program;

(c) apply for approval to analyze at least one analyte or interdependent analyte group by a method the department approves under ARM 37.12.333;

(d) pay all applicable fees prescribed by ARM 37.12.310 prior to the department's processing of the application; and

(e) submit a statement of assurance of compliance signed and dated by the laboratory owner, director, and quality assurance officer, which shall include:

(i) an acknowledgment that the applicant understands that, once licensed, the laboratory must continually comply with the requirements for licensure in this subchapter in order to remain licensed;

(ii) an acknowledgment that the department may make unannounced inspections of the laboratory for the purpose of assessing compliance with these rules and that a refusal to allow entry to the laboratory premises by the department's authorized representatives is grounds for denial or revocation of its license;

(iii) a statement that the applicant laboratory will perform all proficiency testing audits according to acceptable methods, in accordance with department requirements, and at their own expense; and

(iv) a statement that there is no misrepresentation in the information provided in the application.

(2) When the laboratory submits the documentation required by ARM 37.12.333, the department shall conduct an on site assessment at a date and time agreed to by the laboratory director to determine whether the laboratory complies with the minimum requirements of this subchapter and that the laboratory can produce valid results.

(3) At the time of scheduling the assessment, the department's certification officer shall specify what staff, equipment, and supplies need to be on hand during the evaluation and what tests need to be run in order to determine whether the laboratory can meet the licensure requirements set out in this subchapter.

(4) If possible, the evaluations will be scheduled to occur within 45 days after the department determines the application is complete, except in the case of applications received in May, June, July, or August, which will be scheduled for evaluation no later than October 31 of the same year.

(5) The certification officer shall provide the laboratory director with a written report of the department's findings from the on site assessment.

(6) If the department determines that the laboratory does not meet the requirements for licensure:

(a) the department will send the laboratory written notice of that fact, the grounds for the decision, and the right to submit a plan of correction within 30 days after receipt of the notice for minor deficiencies and within 15 days after receipt of the notice for major deficiencies;

(b) if a plan of correction is not received by the deadline or if the plan of correction is inadequate to correct the deficiencies, the department will issue a written denial of the license, the grounds for denial, and the right to an appeal pursuant to the Montana Administrative Procedure Act.

(7) If the on site assessment is satisfactory or, if it is not, if implementation of the plan of correction successfully eliminates the deficiencies cited, the department shall issue a final decision in writing granting the type of license requested and stating which analyte(s) or interdependent analyte group(s) the laboratory is approved to analyze.

(8) A license expires on the expiration date listed on the license, unless revoked earlier. To avoid a lapse in licensure, a laboratory must submit, on a form provided by the department, a completed application for renewal and the required fee for licensure prior to the expiration of the license. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.306 STANDARDS, INSPECTIONS AND TESTS REQUIRED FOR LICENSURE (1) In order to be licensed, a laboratory must:

(a) meet all of the applicable personnel, equipment, training and facility requirements of this subchapter;

(b) at least once during the three year term of its license, pass an on site inspection by an agent of the environmental laboratory that shows compliance with the requirements of these rules for the license category in question; and

(c) if the laboratory performs chemical analyses, have performed analyses on two performance evaluation (PE) samples each year during the term of its license, at least one of which indicates a successful identification of each analyte that it is approved under its license to analyze. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

Rules 07 through 09 reserved

37.12.310 LICENSURE FEES (1) The following fees must be submitted to the department, under the circumstances noted, by laboratories conducting analyses of public water supplies:

(a) $250 with an application for an initial microbiology or chemistry license or renewal of a microbiology or chemistry license;

(b) $150 for an inspection to determine if the holder of a provisional license qualifies for a full license;

(c) $250 plus travel expenses for a second inspection during the three year term of a license that is necessary for approval of a new laboratory location; there is no charge for one inspection during the term of the license;

(d) $300 annually for a chemistry license;

(e) $200 annually for a microbiology license;

(f) $125 per day for training in the environmental laboratory;

(g) $250 per day, plus travel expenses of environmental laboratory staff, for on site training and technical assistance outside of licensure inspections by the environmental laboratory. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 1999 MAR p. 1230, Eff. 6/4/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.311 DURATION OF LICENSE (1) A license granted to an in-state laboratory is for a three year period provided:

(a) all of the requirements of this subchapter continue to be met for the type of license granted;

(b) the laboratory completes annual questionnaires from the department designed to update the department on personnel and procedures; and

(c) the laboratory remits to the department the appropriate annual licensure fee and any other fees due pursuant to ARM 37.12.310.

(2) A reciprocal license granted to an out-of-state laboratory is for the same period as the license, certification or other approval granted by the approving authority, provided that:

(a) all of the requirements of ARM 37.12.313 continue to be met;

(b) the laboratory completes annual questionnaires designed to update the department on personnel and procedures; and

(c) the laboratory remits to the department the appropriate annual licensure fee or fees due pursuant to ARM 37.12.310. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 1999 MAR p. 1230, Eff. 6/4/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.312 PROVISIONAL LICENSE (1) In the case of a laboratory applying for a license for the first time, the department may grant a provisional license to a laboratory that:

(a) is in compliance with all requirements for licensure but has not yet analyzed a second PE sample or does not have records of historical performance; or

(b) does not comply with all of the requirements of this subchapter, but whose deficiencies do not affect the capability of the laboratory to perform valid analyses.

(2) Provisional licensure will be granted only after an on site inspection and is in effect for one year or until full licensure is granted, whichever is earlier.

(3) In order for a laboratory applying for a chemistry license for the first time to upgrade from provisional licensure status to fully licensed status, it must perform analyses of a minimum of two PE samples over the course of a year that indicate at least two successful analyses of each analyte for which they seek licensure to analyze, and undergo a second on site inspection that shows full compliance with licensure standards.

(4) In order for a laboratory applying for a microbiology license for the first time to upgrade from provisional licensure status to fully licensed status, a microbiology laboratory must be in continual operation for one year, accurately analyze any required audit samples, and undergo a second on site inspection to verify that its methodologies and quality control meet the standards of this subchapter. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.313 RECIPROCITY (1) The department may issue a license to an out-of-state laboratory to perform analyses for public drinking water systems in Montana provided that the laboratory:

(a) applies for licensure and is currently approved by the environmental protection agency or the state in which the laboratory is located if that state has a certification program approved by EPA for laboratories analyzing water from public water supplies;

(b) the EPA or the state's certifying authority, whichever is appropriate, provides the department with a copy of the laboratory's current certification and most recent inspection report;

(c) the requirements for certification in the approving state are no less stringent than the requirements for resident laboratories in the state of Montana;

(d) the laboratory submits qualification information for all key personnel and provides the department with a current copy of the laboratory’s quality assurance plan;

(e) the laboratory performs and accurately analyzes PE samples for analytes from sources approved by the department. The provider of the PE samples shall report results of the analyses directly to the department; and

(f) the laboratory complies with the notification requirements of ARM 37.12.324, 37.12.325, and 37.12.326.

(2) The department may license a laboratory that is accredited by the national environmental laboratory accreditation program (NELAP) if:

(a) it provides evidence of its accreditation and applies for licensure on that basis; and

(b) it obtains approval from the department of the testing procedures for each analyte or interdependent analyte group and meets the approval requirements of this rule. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

37.12.314 RESTRICTION OF LICENSE (1) The department may place conditions upon the license of a laboratory under the following circumstances:

(a) the laboratory reports results of an analysis of PE samples that are outside acceptable limits or it fails to report results of a PE sample analysis for any analyte that the laboratory is approved to analyze. In this case:

(i) the laboratory's license is conditional only in regard to the laboratory's approval to conduct analyses of the particular analyte involved;

(ii) the conditional status remains in effect until the next available PE results are reported to the department, at which time:

(A) the conditions will be removed if acceptable PE results are reported to the department; or

(B) approval to conduct the analysis in question will be revoked if unacceptable PE results are reported to the department.

(b) the laboratory notifies the department, after the fact, of changes in personnel, equipment or procedures that have a material effect on the analyses of analytes for which it is approved. In this case, conditional approval will remain in effect until:

(i) the department has re-evaluated the laboratory; and

(ii) those analyses affected by the changes are conducted on PE samples and the results are evaluated by the department, at which time the conditions may be removed if the analyses meet the standards of these rules or approval to do those tests may be revoked if the standards are not met. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.315 REVOCATION OR DENIAL OF LICENSE (1) The department may deny or revoke a license at any time that a laboratory is not in compliance with the requirements for licensure under this subchapter, including if the laboratory:

(a) fails to analyze and report results of at least two PE samples per year;

(b) reports unacceptable results or fails to report the results of analyses of two consecutive PE samples for an analyte for which the laboratory is approved;

(c) fails to correct cited deficiencies within the time specified by the department or fails to adhere to conditions of a waiver or variance;

(d) no longer employs a director or analysts who have satisfied the requirements of this subchapter;

(e) does not use EPA-approved methods to perform analyses;

(f) does not perform required quality control procedures;

(g) falsifies data or engages in deceptive practices such as reporting another laboratory's data without giving credit on the report to the laboratory which performed the analysis;

(h) reports data that were obtained using equipment, procedures, analysts, methods or facilities that are not approved by the department; or

(i) fails to report the results of unsatisfactory test results of samples or maximum contaminant level (MCL) violations to the department of environmental quality as required under ARM Title 17, chapter 38, subchapter 2.

(2) The department will send the laboratory written notice of the denial or revocation of a license that indicates the grounds for the revocation or denial and the right to an appeal of the decision pursuant to the Montana Administrative Procedure Act. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.316 REISSUANCE OF LICENSE (1) The department will issue a license to a laboratory whose license has been denied or revoked when the laboratory demonstrates to the department that all appropriate requirements listed in the EPA laboratory certification manual are satisfied and when a compliance schedule has been set to meet all additional requirements of this subchapter.

(2) If the laboratory does not fulfill the terms of the compliance plan, the license will again be revoked pursuant to ARM 37.12.315.

(3) A laboratory may request technical assistance from the department to remediate any deficiencies. The department shall provide the technical assistance as soon as is practical.

(4) The department adopts and incorporates by reference the EPA laboratory certification manual (EPA 815-B-97-001, "Manual for the Certification of Laboratories Analyzing Drinking Water", March 1997), which contains criteria, procedures, and quality assurance standards required by the environmental protection agency that must be met by laboratories analyzing drinking water to determine compliance with the federal Clean Water Act and its rules. A copy of the manual may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Environmental Laboratory, 1400 Broadway, Cogswell Building, P.O. Box 202951, Helena, MT 59620-2951, telephone: (406) 444-3444. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

Rules 17 through 19 reserved

37.12.320 PROFICIENCY TESTING (1) For a laboratory to become approved and to maintain approval for conducting analyses for an analyte or an interdependent analyte group by a specific method, the laboratory must, at its own expense, meet the proficiency testing requirements of this rule.

(2) In order to initially obtain and to maintain approval, the laboratory must:

(a) whenever required by the EPA, enroll and participate in a proficiency testing program approved by the environmental laboratory for each analyte or interdependent analyte group, or, for each analyte or interdependent analyte group for which proficiency testing is not available or required, the laboratory must establish, maintain and document the accuracy and reliability of its procedures through a quality assurance plan;

(b) participate in at least two proficiency tests annually to be evaluated to obtain or maintain approval to analyze an analyte or interdependent analyte group;

(c) prior to obtaining approval, notify the department of the authorized proficiency testing program or programs in which it has enrolled for each analyte or interdependent analyte group;

(d) follow the proficiency testing provider's instructions for preparing the proficiency testing sample and must analyze the proficiency testing sample as if it were a client sample;

(e) direct the proficiency testing provider to send, either in hard copy or electronically, a copy of each evaluation of the laboratory's proficiency testing audit results to the department; and

(f) authorize the proficiency testing provider to release to the department all information necessary for the department to assess the laboratory's compliance with this rule.

(3) In addition to the requirements of (2), in order to remain approved for testing an analyte or interdependent analyte group, a laboratory must:

(a) in each calendar year, complete at least two separate proficiency testing audits for each analyte or interdependent analyte group;

(b) maintain a copy of all proficiency testing records, including analytical worksheets and a copy of the proficiency testing provider report forms authorized by the environmental laboratory and used by the laboratory to record proficiency testing results;

(c) for every proficiency test, ensure that the director of the laboratory signs and retains an attestation statement stating that the laboratory followed the proficiency sample provider's instructions for preparing the proficiency sample and analyzed the proficiency testing sample as if it were a client sample; and

(d) analyze and report to the provider the results of the proficiency test by the deadline set by the proficiency testing provider.

(4) A laboratory may not:

(a) perform multiple analyses (such as replicates or duplicates) that are not normally performed in the course of analysis of a routine sample;

(b) average the results of multiple analyses for reporting when not specifically required to do so by the analytic method in question;

(c) permit anyone other than bona fide laboratory employees who perform the analyses on a day-to-day basis for the laboratory to participate in the generation of data or reporting of results;

(d) discuss the results of a proficiency testing audit with any other laboratory until after the deadline set for receipt of results by the proficiency testing provider;

(e) if the laboratory has multiple testing sites or separate locations, discuss the results of a proficiency testing audit across sites or locations until after the deadline set for receipt of results by the proficiency testing provider;

(f) send proficiency testing samples or portions of samples to another laboratory to be tested; or

(g) knowingly receive a proficiency testing sample from another laboratory for analysis and fail to notify the department of the receipt of the other laboratory's sample within five business days of discovery.

(5) Results of proficiency tests must be within the control limits established by the EPA as specified in chapter IV of the EPA laboratory certification manual for each analysis for which the laboratory requests approval. These limits are determined by using the known concentration of the analyte in the sample and by the application of accepted statistical procedures.

(6) The department may require the testing of other samples, such as blind samples or split samples, as needed to evaluate laboratory performance.

(7) The laboratory must participate in an authorized proficiency testing program for at least 12 months before changing to another proficiency testing provider for the analyte or interdependent analyte group, unless there are extenuating circumstances.

(8) A laboratory must notify and have approval from the department before changing enrollment in an authorized proficiency testing program, and if the reason for changing providers is a result of extenuating circumstances, the laboratory must also delineate the reasons for the requested change.

(9) The department adopts and incorporates by reference the acceptance limits for regulated parameters in chapter IV of the EPA laboratory certification manual (EPA 815-B-97-001, "Manual for the Certification of Laboratories Analyzing Drinking Water", March 1997), which contains the critical elements for chemistry that a laboratory must meet, including the acceptance limits required by the EPA for metals, inorganics, volatile organic compounds and synthetic organics in drinking water samples. A copy of chapter IV may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Environmental Laboratory, 1400 Broadway, Cogswell Building, P.O. Box 202951, Helena, MT 59620-2951, telephone: (406) 444-3444. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

Rules 21 through 23 reserved

37.12.324 REQUIRED NOTIFICATION OF CHANGES (1) Whenever a laboratory makes any change in personnel, equipment or procedures that has a material effect on the analysis of analytes, the laboratory must notify the department of that fact within 30 days after making the change. A change in personnel is defined as the loss or replacement of the laboratory supervisor or a situation in which a trained and experienced analyst is no longer available to analyze a particular parameter for which licensure has been granted.

(2) After receiving the notification, the department will place conditions upon the laboratory's license pursuant to ARM 37.12.314. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.325 CHANGE IN NAME (1) A licensed laboratory that changes its name or business organizational status must report the change in writing to the department within 30 days of the change. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

37.12.326 CHANGE IN LOCATION (1) A licensed laboratory which intends to change its physical location shall notify the department 90 days prior to the relocation. The notification shall include the following:

(a) the full physical address of the new location;

(b) a notification of any personnel, equipment or analytic method changes which will occur as a result of the relocation; and

(c) a signed statement either that the laboratory quality assurance plan will not be affected by the relocation, or, if it will be, that the plan will be revised to address the necessary changes.

(2) If, in view of the information received pursuant to (1), the department is satisfied that the laboratory can produce valid results at the new location, it shall place conditions on the laboratory license as specified in ARM 37.12.324.

(3) The department shall conduct an on site inspection at the new location within 60 days after the relocation is completed.

(4) Within 30 days after the on site inspection, the department shall issue a determination either that the laboratory license is:

(a) revoked;

(b) its conditional status is retained; or

(c) the conditions are removed.

(5) If the department's decision is to revoke the license, the procedure followed will be that set out in ARM 37.12.315.

(6) The term of the license remains the same as it was for the original site. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.327 ACCESS TO FACILITY AND RECORDS (1) A laboratory applying for a license and a licensed laboratory must allow department representatives access to the laboratory facility and public water supply records during laboratory operating hours to determine initial or continued compliance with this subchapter.

(2) Whenever possible, inspections will be scheduled in advance so that they do not interfere with routine laboratory operations. However, whenever necessary to protect public health, unannounced inspections will be conducted.

(3) If an unannounced inspection causes a business hardship or may result in harm to laboratory clients, the laboratory director will give the department notice of that fact at the time of inspection and the department will make whatever accommodations may be made to alleviate the hardship or harm while still protecting public health. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

Rules 28 and 29 reserved

37.12.330 BLIND SAMPLE TESTING (1) The department may submit blind samples for analyses to a license applicant or a licensed laboratory in such a manner that the applicant or licensed laboratory is unaware of the identity of the submitter. The laboratory shall credit any charges for blind samples to the department when later notified that a sample was a blind sample. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

Rules 31 and 32 reserved

37.12.333 APPROVAL TO CONDUCT ANALYSES (1) Analyses must be conducted using current EPA approved methods in accordance with the analytical requirements set forth in 40 CFR 141.

(2) Alternate analytical procedures are not permitted unless such procedures satisfy 40 CFR 141.27 and have been approved by the EPA.

(3) An applicant laboratory must request approval to analyze for an analyte or interdependent analyte group as part of its application for licensure or renewal of a license.

(4) Approval for such analyses will be granted only after an on site assessment. The applicant laboratory shall submit:

(a) documentation that it has the necessary equipment and qualified technical employees to preform the tests;

(b) for chemistry analysis, documentation that the laboratory has passed two proficiency testing audits for the analyte in question in a proficiency testing program;

(c) its standard operating procedure for the method used to analyze for the analyte in question;

(d) documentation of its initial demonstration of analytical capability; and

(e) documentation establishing the laboratory's method detection limit for each chemical analyte.

(5) If the department is satisfied from its assessment that the applicant laboratory can produce valid results, it shall grant approval for the analyte or interdependent analyte group by a specific method.

(6) At a time other than when applying for a license renewal:

(a) a licensed laboratory may request approval to analyze for an additional analyte or interdependent analyte group by submitting a written request together with the documentation required in (1).

(b) if the analyte for which approval is requested is an addition to, or a group similar to, analytes that have already received approval, the state environmental laboratory may grant a provisional approval for the analyte which shall remain in effect until the next review for license renewal as long as the laboratory continues to successfully complete proficiency testing on the analyte.

(c) If the analyte for which approval is requested is unrelated to previously approved analytes, or requires specialized equipment and/or personnel training, the state environmental laboratory shall require a new application packet and an application fee to be submitted, as well as an update of the laboratory licensure file, and shall perform an on site assessment prior to approval. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

Rules 34 and 35 reserved

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37.12.336 QUALITY ASSURANCE (1) A licensed laboratory must develop and implement a quality assurance program that is an integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that its services meet its standards of quality with its stated level of confidence.

(2) The quality assurance program must address the type of testing activities the licensed laboratory undertakes and how quality assurance activities may change with changes in sample volumes. The quality assurance program must include a quality assurance plan and documentation of quality assurance activities.

(3) As part of its quality assurance program, each licensed laboratory must develop and adhere to a quality assurance plan. The laboratory must include and address the following essential items in the quality assurance plan:

(a) listing of key individuals, laboratory organization and lines of responsibility;

(b) position descriptions;

(c) evaluation of staff competency;

(d) staff training;

(e) general quality control procedures;

(f) frequency of proficiency testing;

(g) proficiency testing audit handling;

(h) reporting of proficiency testing results;

(i) analytical methods and SOPs with annual reviews and dates of revisions of the methods and SOPs;

(j) sample handling procedures;

(k) data reduction, validation, reporting, and verification (an SOP may be referenced);

(l) record keeping, quality assurance review of data, and reporting of results;

(m) equipment operation and calibration;

(n) physical facility factors that may affect quality;

(o) corrective action policy and procedures;

(p) definitions of terms used in the quality assurance plan;

(q) frequency and procedure of quality reviews and the content of reports to the laboratory director; and

(r) frequency, procedure, and documentation of preventive maintenance.

(4) For chemistry laboratories the plan must also include:

(a) calibration procedures for chemistry (an SOP may be referenced);

(b) instrument performance checks;

(c) laboratory reagent blanks, and field or trip blanks;

(d) field or laboratory matrix replicates;

(e) reference samples;

(f) laboratory fortified blanks and laboratory fortified matrix spikes;

(g) initial demonstration of method capability and use of control charts; and

(h) qualitative identification and confirmation of contaminants.

(5) As part of the quality assurance program, the laboratory must document and retain records demonstrating that it has maintained compliance with its quality assurance program. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

37.12.337 SAFETY (1) A laboratory shall develop and maintain a safety program, including an education-based safety program, which meets the requirements of the Montana Safety Culture Act, Title 39, chapter 71, part 15, MCA, and ARM 24.30.2501, 24.30.2503, 24.30.2507, 24.30.2521, 24.30.2541, 24.30.2542, 24.30.2551, 24.30.2553, 24.30.2554 and 24.30.2558 implementing that act and adopted by the department of labor and industry.

(a) The department adopts and incorporates by reference those portions of ARM 24.30.2501, 24.30.2503, 24.30.2507, 24.30.2521, 24.30.2541, 24.30.2542, 24.30.2551, 24.30.2553, 24.30.2554 and 24.30.2558, which contain requirements that employers must meet concerning the establishment of educational safety programs and safety programs for employers who employ more than five employees. A copy of those rules may be obtained from the Department of Public Health and Human Services, Office of Legal Affairs, 1400 Broadway, Cogswell Building, P.O. Box 202951, Helena, MT 59620-2951.

(2) The laboratory shall develop and maintain a chemical hygiene plan.

(3) Where safety methods are included in an analytic method approved by the department, they must be included in the method's SOP and adhered to by the laboratory's analysts performing the procedure. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.338 LABORATORY EQUIPMENT AND SUPPLIES (1) A laboratory must have, at a minimum, the equipment and supplies necessary to perform an approved analytical method for each contaminant analysis for which approval is requested pursuant to ARM 37.12.305.

(2) The equipment and supplies must meet the specifications required by the approved analytical method used and the specifications specified in the EPA laboratory certification manual for that method.

(3) Analytical reagent (AR) grade chemicals or better must be used for analyses.

(4) The laboratory must have a source of distilled or deionized water that meets all the requirements listed in the EPA laboratory certification manual and the requirements of the analytical method being used.

(5) For chemical analyses of drinking water, the laboratory must have a source of reagent water having a specific resistance value of at least 0.5 megohms (less than 2.0 umhos/cm) at 25C. Reagent water for organic analysis must be free of interferences for the analytes being measured.

(6) The department adopts and incorporates by reference the standards contained in the EPA laboratory certification manual (EPA 815-B-97-001, "Manual for the Certification of Laboratories Analyzing Drinking Water", March 1997) for sources of distilled or deionized water. A copy of the manual may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Environmental Laboratory, 1400 Broadway, Cogswell Building, P.O. Box 202951, Helena, MT 59620-2951, telephone: (406) 444-3444. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

Rules 39 and 40 reserved

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37.12.341 REPORTING REQUIREMENTS (1) Reporting requirements for laboratories performing microbiological or chemical analyses of water from public water supplies are as follows:

(a) All analyses of samples not meeting the requirements of ARM Title 17, chapter 38, subchapter 2 must be promptly, on that day or no later than noon of the next working day, reported by telephone to the department of environmental quality (DEQ) (phone (406) 444-5313 for chemistry results and (406) 444-3425 for microbiology results);

(b) When a maximum contaminant level set out in ARM Title 17, chapter 38, subchapter 2 is found to be exceeded in any sample, the laboratory must notify the water supplier within 24 hours after the analysis is completed and request resampling from the sampling point according to the requirements of ARM Title 17, chapter 38, subchapter 2, with the exception noted in (1)(c);

(c) If a test shows a positive total coliform, fecal coliform or E. coli result, a laboratory must immediately notify the supplier and within 24 hours notify the DEQ of that fact. A total coliform-positive result is based on a confirmed phase for the multiple tube fermentation technique and presence-absence (P-A) coliform test or verified test for membrane filter technique. No requirement exists for confirmation of positive Colilert/Colisure tests, fecal coliform tests or E. coli tests. In those rare cases where a presumptive total coliform-positive culture does not confirm or verify as such, but is found to be fecal coliform or E. coli positive, the sample is considered total coliform-positive and fecal coliform/E.coli positive;

(d) Written reports of contaminated microbiological samples must be sent to the DEQ within 48 hours after the test is completed; and

(e) Written reports of all microbiological samples other than those which are contaminated must be sent to the DEQ within five days after the tests are completed. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.342 REPORTING RESULTS FROM OTHER LABORATORIES

(1) A laboratory that reports analyses from other laboratories must report all such laboratory results on the original reporting document, or a copy thereof, of the other laboratory performing the analyses and must attest that the laboratory performing the analyses is a laboratory licensed to perform drinking water analysis in Montana. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99.)

Rules 43 and 44 reserved

37.12.345 CRITICAL ELEMENTS FOR CHEMISTRY LABORATORY LICENSURE (1) In order to be licensed to perform chemical analyses, a laboratory must meet the standards contained in this rule.

(2) Analysts in training must be supervised by an experienced analyst who meets all of the requirements of this rule.

(3) Supervising analysts must verify all results of testing performed by analysts in training and cosign those results.

(4) The laboratory's analysts must:

(a) meet all of the qualifications and conditions set forth in chapter IV of the EPA laboratory certification manual, except those noted in (5) and (6); and

(b) if operating the following, have the training noted, unless the department approves a specialized training course as a substitute:

(i) if using a gas chromatograph, liquid chromatograph, mass spectrometer or an inductively coupled plasma atomic emission spectrophotometer, have satisfactorily completed a short course in their operation offered by the equipment manufacturer, a professional organization, a university or another department-approved training facility acceptable to the department; and

(ii) if operating an atomic absorption, an ion chromatograph, a gas chromatograph or an inductively coupled plasma atomic emission spectrophotometer, have a minimum of six months previous experience in their operation;

(iii) if operating a gas chromatograph or mass spectrometer, have a minimum of 12 months previous experience in its operation.

(5) A test for ortho-phosphate may not be filtered.

(6) The wavelength settings of variable wavelength spectrophotometers must be verified quarterly with color standards.

(7) The department adopts and incorporates by reference chapter IV of the EPA laboratory certification manual (EPA 815-B-97-001, "Manual for the Certification of Laboratories Analyzing Drinking Water", March 1997), which establishes qualifications for staff training and experience and conditions for approval of laboratories conducting chemical analyses of public drinking water. A copy of chapter IV may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Environmental Laboratory, 1400 Broadway, Cogswell Building, P.O. Box 202951, Helena, MT 59620-2951. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

37.12.346 CRITICAL ELEMENTS FOR MICROBIOLOGY LABORATORY LICENSURE (1) In order to be licensed to perform microbiological analyses, a laboratory must meet the standards contained in this rule.

(2) Individual analysts must be approved by the state as meeting the standards of this rule in order to perform microbiological analysis of drinking water samples.

(3) Analysts in training must be supervised by an experienced analyst who meets all of the requirements of this rule.

(4) Supervising analysts must verify all results of testing performed by analysts in training and co-sign those results.

(5) A laboratory must meet all of the qualifications and conditions set forth in chapter V of the EPA laboratory certification manual, except that:

(a) the first sentence of paragraph 6.4 is replaced by the following:

"The Total Coliform Rule (TCR), 40 CFR 141.21(f)(3) and EPA's Manual for the Certification of Laboratories Analyzing Drinking Water, Fourth Edition, March 1997, limit the time from sample collection to initiation of analysis to 30 hours. Public water systems (PWSs) must make every effort to meet the 30 hour holding time requirement. Laboratories may continue to analyze samples that are up to 48 hours old with the following two additional requirements:

1. Laboratories must flag samples that are greater than 30 and less than or equal to 48 hours old.

2. Laboratories must continue to invalidate a total coliform negative sample that shows signs of heterotrophic interference (40 CFR 141.21(c)(2)) regardless of the holding time. However, replacement samples may not exceed 30 hours."; and

(b) analysts must have a minimum of four days of training at the environmental laboratory with a successful evaluation from the state training personnel, with the exception that up to two days training may be waived at the discretion of the microbiology certification officer based upon education and experience of the analyst.

(6) Each membrane filter lot must be checked by comparing recovery of coliform organisms against membrane filters from a previously acceptable lot.

(7) The department adopts and incorporates by reference chapter V of the EPA laboratory certification manual (EPA 815-B-97-001, "Manual for the Certification of Laboratories Analyzing Drinking Water", March 1997), which establishes qualifications for staff training and experience and conditions for approval of laboratories conducting microbiological analyses of public drinking water. A copy of chapter V may be obtained from the Department of Public Health and Human Services, Public Health and Safety Division, Environmental Laboratory, 1400 Broadway, Cogswell Building, P.O. Box 202951, Helena, MT 59620-2951. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202 and 75-6-106, MCA; NEW, 1999 MAR p. 291, Eff. 2/12/99; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

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Subchapter 4

Fees for Laboratory Analyses

37.12.401 LABORATORY FEES FOR ANALYSES (1) Fees for clinical analyses performed by the laboratory of the department of public health and human services are as follows, with the exception noted in (3):

	Fee
(a) Microbiology Tests	
(i) Anaerobic Culture	$ 30.83
(ii) Autoclave Monitor	16.22
(iii) Bacterial Culture	28.66
(iv) Bacterial Screen	23.80
(v) C Diff Toxin	21.20
(vi) Chemclave Monitor	16.22
(vii) Chlamydia Amplification	18.93
(viii) EHEC Toxin	21.20
(ix) Enteric Panel	28.66
(x) Gonorrhea Amplification	18.93
(xi) Pertussis DFA	19.03
(xii) Legionella DFA	19.03
(b) Miscellaneous Test	
(i) Test sent out	8.11
(ii) Dangerous goods	54.08
(c) Mycology Tests	
(i) Fungal Culture, Skin	30.46
(ii) Fungal Culture, Other	30.46
(iii) Fungal Culture, Blood	30.46
(d) Newborn Tests	
(i) IRT (Cystic Fibrosis)	9.88
(ii) Galactose	11.10
(iii) PKU	10.19
(iv) Hemoglobinopathy	8.17
(v) Thyroxine	9.88
(vi) TSH	8.71
(e) Parasitology Tests	
(i) Crypto/Cyclo stain	22.93
(ii) O & P Conc. ID	12.44
(iii) O & P, Trichrome	10.49
(f) Serology Tests	
(i) Blood Lead	16.22
(ii) Brucella	14.87
(iii) CMV, IgG	16.44
(iv) CMV, IgM	29.53
(v) Colorado Tick Fever	16.44
(vi) FTA	26.72
(vii) Hantavirus IgG	37.00
(viii) Hantavirus IgM	37.00

(ix) Hepatitis A IgM	$ 25.00
(x) Hepatitis B core IgM	25.00
(xi) Hepatitis B Antibody	19.25
(xii) Hepatitis B core total	28.66
(xiii) Hep B Surface Antigen	17.09
(xiv) Hepatitis C	28.66
(xv) Herpes simplex 1 & 2	32.88
(xvi) HIV screen	13.84
(xvii) HIV Western Blot	96.00
(xviii) Legionella	16.44
(xix) Mumps	16.44
(xx) Q Fever	16.44
(xxi) RMSF	16.44
(xxii) Rubella	16.44
(xxiii) Rubeola	16.44
(xxiv) Tularemia	14.87
(xxv) Toxo IgG	16.44
(xxvi) Toxo IgM	29.53
(xxvii) Varicella Zoster	16.44
(xxviii) VDRL, qua	10.83
(xxix) West Nile Virus	15.00
(xxx) VDRL, quant	10.98
(xxxi) SLE	15.00
(g) Tuberculosis Tests	
(i) Acid Fast Stain	11.46
(ii) Mycobact. Culture	17.01
(iii) Mycobact. Concentration	9.59
(iv) Mycobact. Suscept., each drug	12.00
(v) Mycobact. Sp. Probe	19.03
(vi) Mycobact. Avium Probe	19.03
(vii) Mycobact. TB Probe	19.03
(viii) Mycobact. TB AMP	145.60
(h) Virology Tests	
(i) Chlamydia Culture	30.50
(ii) Herpes Culture	20.00
(iii) Direct Detection (RSV, VZV, HSV)	19.03
(iv) Virus ID (IFA)	9.52
(v) Viral Culture	30.50
(vi) Virus ID (neutralize)	40.00
(i) Molecular Testing	
(i) PCR, 1 agent	60.00
(ii) PFGE, 1 enzyme	66.25
(iii) Hep C, PCR	101.92

(2) Effective December 1, 2003, fees for environmental analyses performed by the laboratory of the department of public health and human services are as follows, with the exceptions noted in (3) and (4):

(a) Fees for nutrient analyses are as follows:	
(i) Nitrate plus nitrate as N	$ 14.50
(ii) Nitrite	14.50
(iii) Ortho phosphorus	14.50
(iv) Soluble phosphorus	14.50
(v) Total ammonia as N	14.50
(vi) Total phosphorus	24.75
(vii) Total kjeldahl nitrogen	28.75
(b) Fees for metal analysis by ICP are as follows:	
(i) Aluminum	9.20
(ii) Antimony	17.25
(iii) Arsenic	17.25
(iv) Barium	9.20
(v) Beryllium	9.20
(vi) Bismuth	9.20
(vii) Boron	9.20
(viii) Calcium	9.20
(ix) Cadmium	9.20
(x) Cobalt	9.20
(xi) Copper	9.20
(xii) Chromium	9.20
(xiii) Dust wipes	18.00
(xiv) Iron	9.20
(xv) Lead	17.25
(xvi) Lithium	9.20
(xvii) Magnesium	9.20
(xviii) Manganese	9.20
(xix) Metals scan, water, 17 element	34.50
(xx) Metals scan, water, 25 element	86.25
(xxi) Metals scan, solids, 20 element	63.25
(xxii) Molybdenum	9.20
(xxiii) Nickel	9.20
(xxiv) Potassium	9.20
(xxv) Silicon	9.20
(xxvi) Silver	9.20
(xxvii) Sodium	9.20
(xxviii) Strontium	9.20
(xxix) Tin	9.20
(xxx) Titanium	9.20
(xxxi) Vanadium	9.20
(xxxii) Zinc	9.20
(xxxiii) Selenium	17.25
(xxxiv) Thallium	17.25

(c) Fees for organic analyses are as follows:	
(i) Organic analyses in drinking water:	
(A) 505 - Organohalide pesticides	$ 172.50
(B) 508 - Chlorinated pesticides	172.50
(C) 515 - Chlorophenoxy herbicides	149.50
(D) 525 - Synthetic organic compounds	276.00
(E) 531 - Carbamate pesticides	172.50
(F) Haloacetic acids	149.50
(G) Trihalomethanes	103.50
(H) VOC - volatile organic compounds	126.50
(ii) For organic analyses in other substrates, EPA 600 and 8000 series, the fees are:	
(A) Organohalide pesticides	230.00
(B) Chlorinated pesticides	230.00
(C) Chlorophenoxy herbicides	265.00
(D) Synthetic organic compounds	276.00
(E) Carbamate pesticides	230.00
(F) Haloacetic acids	207.00
(G) Trihalomethanes	150.00
(H) VOC - volatile organic compounds	276.00
(d) Fees for fuel analyses are as follows:	
(i) Blue dye in fuel	8.63
(ii) Red dye in fuel	8.63
(iii) Dyed fuel combo (excludes blue dye in fuel)	55.00
(iv) Diesel characterization	34.50
(v) Sulfur by XRF	23.00
(e) Fees for commons are as follows:	
(i) Alkalinity	15.00
(ii) Chloride	20.00
(iii) Conductivity	6.90
(iv) Fluoride	17.25
(v) pH	6.90
(vi) Sulfate	20.00
(vii) TDS	9.20
(viii) TSS	9.20
(ix) Volatile suspended solids	25.76
(f) Fees for air quality analyses are as follows:	
(i) Dustfall	34.50
(ii) Fiberglass hi vol filters	7.00
(iii) PM 10	7.00
(iv) PM 2.5	17.25
(v) PM 2.5p	23.00
(vi) Lead analysis on filters	19.55
(g) Fees for miscellaneous tests are as follows:	
(i) Acidity	14.50

(ii) BOD	$ 40.25
(iii) Chlorophyll	31.75
(iv) CBOD	40.25
(v) COD	40.25
(vi) Color	23.00
(vii) Cyanide - drinking water	40.25
(viii) Hardness	20.70
(ix) Hexavalent chromium	28.75
(x) Mercury	41.40
(xi) Mercury composited	14.50
(xii) Oil and grease	51.75
(xiii) Phenol	28.75
(xiv) Sulfide	40.25
(xv) TOC	29.90
(xvi) Turbidity	6.90
(h) Fees for microbiology testing are as follows:	
(i) Total coliform	19.00
(ii) Fecal coliform - membrane filtration	19.00
(iii) Iron bacteria	19.00
(iv) Sulfur bacteria	19.00
(v) Heterotrophic plate count	19.00
(i) Fees for special handling are as follows:	
(i) Rush fee - per sample order	10.00
(ii) Microwave digestion	19.55
(iii) Nutrient extraction	15.00
(iv) Total metals digestion	17.25
(v) Total recoverable metals digestion	11.50
(vi) VOC extraction - TCLP	57.50
(vii) Metals extraction - TCLP	51.75

(3) The fees specified in (1) and (2) will be lowered by the department of public health and human services to a level not exceeding the cost to the department of the test in question whenever a change of analysis method warrants lower fees.

(4) Fees for analyses other than those listed in (1) and (2) will be established at the level of comparable analyses. (History: Sec. 50-1-202, MCA; IMP, Sec. 50-1-202, MCA; NEW, 1997 MAR p. 1041, Eff. 6/24/97; AMD, 1998 MAR p. 671, Eff. 3/13/98; AMD, 1999 MAR p. 1229, Eff. 6/4/99; AMD, 2000 MAR p. 1663, Eff. 6/30/00; TRANS, from DHES, 2001 MAR p. 2246; AMD, 2003 MAR p. 2442, Eff. 10/31/03; AMD, 2003 MAR p. 2551, Eff. 11/14/03.)

Subchapter 5 reserved

Subchapter 6

Premarital Serological Tests

37.12.601 CERTIFICATE FORM (1) In addition to the information required by 40-1-203 and 40-1-204, MCA, the certificate form shall include the following:

(a) an indication by the certifying physician that either:

(i) the applicant submitted to a standard serological test for rubella immunity within the past six months and that both the applicant and the other party to the proposed marriage have examined the report of such test; or

(ii) the applicant is exempt from the requirement for serological testing on medical grounds, as specified in ARM 37.12.608;

(b) certification by the applicant; and

(c) acknowledgment of receipt of the certificate by the clerk of the district court who is to issue the marriage license. (History: Sec. 40-1-206, MCA; IMP, Sec. 40-1-203 and 40-1-204, MCA; NEW, 1983 MAR p. 1353, Eff. 9/30/83; TRANS, from DHES, 2001 MAR p. 2246; AMD, 2003 MAR p. 2442, Eff. 10/31/03.)

Rule 02 reserved

37.12.603 PROCEDURES (1) The procedure for completion of the medical certificate when the examination is made in Montana is as follows:

(a) The female applicant for a marriage license shall consult a physician for blood tests. If the applicant is not exempt on medical grounds, as set out in ARM 37.12.608, the physician shall send a specimen of the applicant's blood to an approved laboratory designating that it is for a premarital test.

(b) The laboratory shall examine the specimen, fill out the lower half of the certificate form and transmit it with a confidential report of results to the physician.

(c) After examination of the laboratory report and after the report has been exhibited to and examined by the applicant and the other party to the marriage, the physician shall complete the form and give it to the applicant.

(d) The applicant must sign the certificate and present it with satisfactory evidence of age, or if a minor, with the consent required by 40-1-203, MCA, to the clerk of the district court who is to issue the marriage license.

(2) The procedure for completion of the medical certificate when the examination is made outside of Montana is as follows:

(a) Certificate forms and blood test forms have been forwarded to each state health department and are available at these sources or directly from the Department of Public Health and Human Services, Public Health and Safety Division, Environmental Laboratory, 1400 Broadway, Cogswell Building, P.O. Box 202951, Helena, MT 59620-2951.

(b) The applicant may consult any duly licensed physician in any state or territory or Canadian province for the examination.

(c) Blood tests made outside Montana must be done in approved laboratories, which include state and territorial health department laboratories and laboratories within their jurisdictions approved by them, U.S. public health service laboratories, laboratories operated by the U.S. armed forces and veteran's administration, provincial public health laboratories of Canada and laboratories licensed under the provisions of the Clinical Laboratories Improvement Act of 1967.

(d) Certificate forms provided by other states having comparable laws will be accepted for persons who have received serological tests outside of Montana provided such tests are performed not more than six months prior to the issuance of a marriage license. (History: Sec. 40-1-206, MCA; IMP, Sec. 40-1-203, 40-1-204 and 40-1-206, MCA; NEW, 1983 MAR p. 1353, Eff. 9/30/83; TRANS, from DHES, 2001 MAR p. 2246; AMD, 2003 MAR p. 2880, Eff. 10/31/03.)

Rules 04 through 07 reserved

37.12.608 EXEMPTIONS FROM REQUIREMENT FOR SEROLOGICAL TESTING (1) A female applicant for a marriage license may be exempted from the requirements for serological testing on any of the following grounds:

(a) If the applicant is over age 50.

(b) If, in the opinion of the consulting physician, the applicant is incapable of bearing children.

(2) If the consulting physician determines that a basis for exemption exists, he or she shall so indicate on the medical certificate. (History: Sec. 40-1-206, MCA; IMP, Sec. 40-1-206, MCA; NEW, 1983 MAR p. 1353, Eff. 9/30/83; TRANS, from DHES, 2001 MAR p. 2246.)

Subchapter 7 reserved

Subchapter 8

Prenatal Care Serological Tests

37.12.801 APPROVED TESTS (1) The approved tests shall include a standard serological test for syphilis, rubella immunity, and blood group including O, A, B, AB, and Rho(D). (History: Sec. 50-19-101, MCA; IMP, Sec. 50-19-101, MCA; NEW, Eff. 1/5/74; TRANS, from DHES, 2001 MAR p. 2246.)

37.12.802 APPROVED LABORATORY (1) The required prenatal tests shall be done in a laboratory approved by the department of public health and human services. (History: Sec. 50-19-104, MCA; IMP, Sec. 50-19-104, MCA; NEW, Eff. 1/5/74; TRANS, from DHES, 2001 MAR p. 2246.)

Chapters 13 through 24 reserved